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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/687,593	10/13/2000	Osamu Tetsu	M-9005 US	9434

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[REDACTED] EXAMINER

KATCHEVES, KONSTANTINA T

ART UNIT	PAPER NUMBER
1636	[REDACTED]

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/687,593	TETSU ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Konstantina Katcheves	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.  
 2a) This action is **FINAL**.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_ is/are allowed.  
 6) Claim(s) 1-20 is/are rejected.  
 7) Claim(s) \_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved by the Examiner.  
     If approved, corrected drawings are required in reply to this Office action.  
 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All b) Some \* c) None of:  
 1.) Certified copies of the priority documents have been received.  
 2.) Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3.) Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.  
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) The translation of the foreign language provisional application has been received.  
 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____.<br> |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)     |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>14</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1-20 are pending in the present application. Claims 21 and 94 were cancelled by Paper No. 18, filed 12 March 2003. This Office action is in response to the amendment and response of Paper No.18, filed 12 March 2003.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12 March 2003 has been entered.

#### ***Response to Amendment***

The rejections of claims 21 and 94 are moot in view of the cancellation of these claims in Paper no. 18.

Claims 1, 2, 6, and 10-12 stand rejected under 35 U.S.C. 102(e) as being anticipated by Karin et al (USP 6,242,253) for reasons of record and as further discussed below.

Claims 1-12 and 19-20 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Karin et al as applied to claims 1, 2, 6, and 10-12 and further in view of Sadowski et al (USP 5,885,779), Young (Biology of Reproduction (1998) 58:302-311) and Finley et al (in The Yeast Two-Hybrid System, eds. P. Bartel, S. Fields, Oxford University Press, (1997) pp. 197-214) for reasons of record and as further discussed below.

Claims 1-20 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Barker et al (USP 5,851,775), in view of Sadowski et al, Young, Finley et al, Hagahara et al (Nature Medicine (1998) 4:1449-1452) and Schwarze et al (Science (1999) 285:1569-1572) for reasons of record and as further discussed below.

***Response to Arguments***

Claims 1, 2, 6, and 10-12 stand rejected under 35 U.S.C. 102(e) as being anticipated by Karin et al (USP 6,242,253). Applicant provides two arguments in response of the present rejection: (1) Applicant proposes that Karin et al. fail to teach the screening method with a "mammalian cell" and (2) Applicant asserts that Karin et al. fail to teach a metabolic degradation product.

First, as discussed in the Office action mailed 04 December 2001, Karin et al teach using a two hybrid assay to screen for agents that alter the association of I<sub>K</sub>B kinase with a second protein, such as I<sub>K</sub>B or a regulatory protein. Moreover, the screening function interactions is taught in 293 cells. See entire document, especially col. 3, lines 38-56, col. 19, line 41-col. 20, line 17, col. 21, lines 31-50, col. 25, lines 8-60, col. 26, lines 39-49 and col. 35, line 11-17. 293 cells are known in the art to be mammalian cells. Therefore, Karin et al. does indeed meet this limitation of the claims.

Second, the steps in the pending claim are identical to those taught in Karin et al. It is assumed therefore that the same goal will be achieved. This assumption is supported by Applicant's specification on the first full paragraph of page 15 teaching that when no complex is formed between the two hybrid proteins, then there is no signal from the effector gene. This

phenotype is precisely what would be observed for an agent that alters the association between the two hybrid proteins such that they cannot interact. See for instance col. 25, lines 51-53 Karin et al. Furthermore, if an agent inhibits the kinase activity of IKK, then the metabolic product that would accumulate would be, for instance, unphosphorylated I $\kappa$ B. Thus, the teachings of Karin et al inherently teach the accumulation or degradation of a metabolic product as a result of screening for an agent that alters the association between the two hybrid proteins.

Claims 1-12 and 19-20 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Karin et al as applied to claims 1, 2, 6, and 10-12 and further in view of Sadowski et al., Young and Finley et al. Applicant argues that Sadowski et al., Young and Finley et al. fail to satisfy the asserted deficiencies of Karin et al. and thus fail to render the invention obvious. However, in view of the above arguments regarding Karin et al., the present claims stand rejected under 35 U.S.C. 103(a).

Claims 1-20 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Barker et al (USP 5,851,775), in view of Sadowski et al, Young, Finley et al, Hagahara et al (Nature Medicine (1998) 4:1449-1452) and Schwarze et al (Science (1999) 285:1569-1572). Again, Applicant argues that Barker et al. fail to teach the screening method with mammalian cells. Contrary to Applicant's assertion, Barker does indeed teach a mammalian two hybrid system. For instance, carcinoma cell lines including SW480, SW620, DLD-1 and HT29-APC<sup>-/-</sup> were exemplified and taught in Barker et al. See column 8, line 56 and especially column 9, line 12. Thus, Barker et al. teaches this limitation and the Sadowski et al, Young, Finley et al, Hagahara

et al Schwarze et al. are cited for the reasons already of record and need not correct this asserted deficiency in Barker et al.

***Rejection Necessitated by Applicant's Amendment***

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant has amended claim 1 to recite the phrase "a degradation deficiency of the metabolic product." It is understood that *ipsis verbis* support is not required. See *Martin v. Johnson*, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972). However, the term must be exemplified in such a way to provide support and reasonably convey that Applicant had possession of the claimed subject matter. Applicant has also cited a number of pages in support of this amendment. However, it is not immediately apparent that support exists for the amendment filed by Applicant. Ample support exists in the specification for metabolic products and degraded metabolic product, but it is not immediately apparent that support for "a

degradation deficiency of the metabolic product” exists. The concept that Applicant is trying to convey is not clearly exemplified in such a way to support the amendment to the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the language “a degradation deficiency of the metabolic product.” It is not at all clear from the specification what Applicant means by this phrase. The definitions on pages 6-12 of the specification identify and define a “metabolic product.” However, no definition or support is found regarding what Applicant intends “a degradation deficiency of the metabolic product” to mean. Is this merely an accumulation of a degraded metabolic product or is it something else entirely. Moreover, the pages cited by Applicant in support of this phrase neither define it nor exemplify it in any way.

### *Conclusion*

This is a continued examination of applicant's earlier Application No. 09/687593. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a

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first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (703) 305-1999. The examiner can normally be reached on Monday through Friday 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3388.

Konstantina Katcheves  
May 13, 2003

JAMES KETTER  
PRIMARY EXAMINER